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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 101

[Docket No. 98P-0043]

Food Labeling: Nutrition Labeling of Dietary Supplements on a “Per Day” Basis

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to amend its nutrition labeling regulations for dietary supplements to provide that the quantitative amount and the percent of Daily Value of a dietary ingredient may be voluntarily presented on a “per day” basis in addition to the required “per serving” basis, if a recommendation is made on the label that the dietary supplement be consumed more than once per day. This proposal responds to a citizen petition requesting that these regulations be modified to include this provision. FDA is proposing this action to provide manufacturers of dietary supplements flexibility to voluntarily present additional label information to consumers.

DATES: Submit written comments by *(insert date 75 days after date of publication in the Federal Register)*. Submit written comments on the information collection provisions by *(insert date 30 days after date of publication in the Federal Register)*. See section IX of this document for the effective date of any final rule that may issue based on this proposal.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit written comments on the information collection provisions to the Office of Information and Regulatory

Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., Washington, DC 20503, ATTN: Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT: Carole L. Adler, Center for Food Safety and Applied Nutrition (HFS-165), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-205-5494.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of September 23, 1997 (62 FR 49826), FDA published a final rule entitled “Food Labeling; Statement of Identity, Nutrition Labeling and Ingredient Labeling of Dietary Supplements; Compliance Policy Guide. Revocation” (hereinafter referred to as the “September 23, 1997, final rule”). This document was published in response to the Dietary Supplement Health and Education Act of 1994 (the DSHEA) and established requirements for the identification of dietary supplements and for their nutrition labeling and ingredient labeling. These regulations provide, in part, that quantitative information be listed “per serving” and voluntarily “per unit.” The effective date of the September 23, 1997, final rule is March 23, 1999.

In the November 27, 1991, proposed rule on nutrition labeling entitled “Food Labeling; Reference Daily Intakes and Daily Reference Values; Mandatory Status of Nutrition Labeling and Nutrient Content Revision” (56 FR 60366 at 60382), the agency suggested that the required nutrition information for dietary supplements be provided in “units” and “units per day” if label directions advise consumption of more than one unit per day. The agency believed that, because more than one unit of a supplement is often consumed per day, the daily amount recommended by the manufacturer for consumption should be clearly stated. As addressed in the January 6, 1993, final rule entitled “Food Labeling: Mandatory Status of Nutrition Labeling and Nutrient Content Revision, Format for Nutrition Label” (58 FR 2079 at 2168), the agency received several comments opposing dual labeling (i.e., “per unit” and “per day”) of nutrition information if more

than one unit is specified for consumption per day. Comments were opposed for various reasons, including that dual declaration may create consumer confusion, overcrowd labels, and discriminate against supplements that do not provide “units per day” information. The agency was persuaded that dual declaration may create a readability problem for consumers, given the limited space available on most dietary supplements, and that recommended daily consumption of other than well-defined dosages (e.g., “consume 1 to 3 tablets per day”) would pose a problem in terms of labeling on a “per day” basis. The agency tentatively concluded that labeling “per unit” would be more useful in that the product would always be consumed “per unit,” and that consumers may not always follow the manufacturer’s recommendations to consume a certain number of units per day of the product. The agency planned to propose that nutrition information be provided “per unit” in its future rulemaking required by the Dietary Supplement Act (the DS act) (see 58 FR 2079 at 2169).

In the interim, FDA reexamined this issue, and in its June 18, 1993, proposal entitled “Food Labeling; General Requirements for Nutrition Labeling for Dietary Supplements of Vitamins, Minerals, Herbs, or Other Similar Nutritional Substances” (58 FR 33715 at 33716), tentatively concluded that quantitative information should be presented “per serving” rather than “per unit.” The agency explained in this document that consumers might be confused by a “per unit” declaration when more than one unit is to be consumed at one time (e.g., two capsules with each meal) because they might assume that the “per unit” information represents the amount specified for consumption at one time (i.e., “per serving”) similar to conventional foods. The agency also noted that it preferred one consistent method of labeling for the various forms of supplements and that “per unit” labeling was not as appropriate for supplements that do not come in discrete units (e.g., liquid or powdered supplements). Therefore, the agency proposed that quantitative information be provided on a “per serving” basis consistent with §101.9 (21 CFR 101.9). The agency maintained this requirement in the January 4, 1994, final rule entitled “Food Labeling;

General Requirements for Nutrition Labeling for Dietary Supplements of Vitamins, Minerals, Herbs, or Other Similar Nutritional Substances-’ (59 FR 354 at 359).

The DSHEA added section 403(q) (5)(F)(ii) (21U.S.C. 343(q) (5)(F)(ii)) to the Federal Food, Drug, and Cosmetic Act (the act). This section specifies that the listing of dietary ingredients in nutrition labeling shall include the quantity of each such ingredient “per serving.” Therefore, in its December 28, 1995, proposal entitled “Food Labeling; Statement of Identity, Nutrition Labeling and Ingredient Labeling of Dietary Supplements” (60 FR 67194 at 67 198), FDA proposed in § 101.36(b) (2)(ii) (21 CFR 101.36(b) (2)(ii)) that quantitative information be listed on a “per serving” basis. This requirement was unchanged in the September 23, 1997, final rule (62 FR 49826 at 49830). However, the agency was persuaded that there may be some products in which the unit amount may be of interest to consumers, and, therefore, added § 101.36(b)(2)(iv) to provide for quantitative information to be presented voluntarily on a “per unit” basis in addition to the required “per serving” basis in § 101.36(b)(2)(ii) (62 FR 49826 at 49830).

II. Citizen Petition

The Nutrilite Division of Amway Corp., (hereinafter referred to as “the petitioner”), submitted a citizen petition (filed January 23, 1998, Docket No. 98 P-0043/CP1), requesting that FDA amend its nutrition labeling regulations for dietary supplements to permit the option of listing the quantitative amount and the percent of Daily Value of dietary ingredients on a “per day” basis in addition to the required “per serving” basis if the label of the product advises that the dietary supplement be consumed more than once per day.

Specifically, the petitioner requested that FDA redesignate paragraphs (e)(9) and (c)(10) of §101.36 as (e)(IO) and (c)(1 1). In place of former paragraph (e)(9) of §101.36, the petitioner requested that a new § 101.36(e)(9) state:

If the labeling for a dietary supplement recommends that more than one serving be consumed per day, the text of the “Supplement Facts” may also declare the total quantitative amount and the total percent of the Daily Value that will be consumed per day of each dietary ingredient. This additional information

shall be provided in separate columns or other separate placement, but in the same type size and same format employed for the rest of the “Supplement Facts” Information, and shall be introduced by the headings “Total Amount Per Day” and “Total % DV Per Day”.

The petitioner noted that the labels of some dietary supplements recommend consumption of more than one per day, for instance, in the morning and in the evening (i. e., two times a day), or with breakfast, lunch, and dinner (i.e., three times a day). The petitioner asserted that for safety reasons, the consumer should be provided with information about the quantitative amount and the percent of the Daily Value of each dietary ingredient to be consumed per day.

The petitioner stated that it recognizes that the DSHEA provides that the listing of dietary ingredients be on a “per serving” basis, but that does not prevent FDA from allowing information about the quantity of each dietary ingredient consumed per day to be declared voluntarily.

The petitioner maintained that providing additional columns of information to augment the basic nutrition labeling information would not be confusing or misleading, is consistent with the nutrition labeling regulations for dietary supplements, and would not conflict in any way with the required information. The petitioner noted that FDA has already authorized additional columns of information in other circumstances for dietary supplements (e.g., when a product contains two or more separately packaged dietary supplements that differ from each other (§ 101.36(e)(8) and (c)(10)(iii)), and dietary information may be provided on a “per unit” basis in addition to a “per serving” basis (§ 101.36(b)(2)(iv)). The petitioner also provided examples of situations when additional columns for conventional foods may be used (e.g., two or more forms of the same food, and food commonly combined with other ingredients or that is cooked or otherwise prepared before eating may be presented “as purchased” and “as prepared” (§ 101.9(e) and (h)(4)).

The petitioner noted that § 101.9(b)(11) provides that if a product is promoted on the label, or in labeling or advertising for a use that differs in quantity by twofold or greater from the use upon which the reference amount in § 101.12(b) (21 CFR 101.12(b)) was based, then the manufacturer shall provide a second column of nutrition information based on the amount

customarily consumed in the promoted use. in addition to the nutrition information per serving derived from the reference amount in § 101.12(b). According to the petitioner, this provision, which § 101.36(b) references, includes the voluntary declaration of nutrition information for dietary supplements on a ‘ ‘per day’ ’ basis if the label recommends consumption more than once per day.

111. The Proposal

The agency acknowledges that it had previous concerns about quantitative information for dietary supplements being presented on a “per day” basis, and has discussed them in section I of this document. However, the agency is persuaded by the petitioner that this additional information may be useful to impress upon consumers of dietary supplement products the total daily intake of each dietary ingredient they will receive from a product that is recommended for consumption multiple times per day. Therefore, the agency tentatively concludes that if the labeling of a dietary supplement recommends consumption more than once per day, it would be acceptable to provide quantitative information “per day” in addition to ‘ ‘per serving’ ’ when the product label has sufficient space available to present this information in accordance with the format requirements specified in § 101.36(e) or the special labeling provisions for small and intermediate-sized packages in § 101.36(i)(2).

The agency does not agree that this provision is covered by § 101.9(b)(11). That paragraph refers to usage at one eating occasion of a quantity that differs by twofold from the quantity upon which the reference amount was based, not to the usage over a day’s time.

The agency agrees with the petitioner that it is appropriate to place this provision in § 101.36(e), which is the section pertaining to the presentation of nutrition information. In doing so, the agency is proposing to remove paragraph § 101.36(b)(2)(iv), which provides for the optional listing of quantitative information on a “per unit” basis and include this provision in a new § 101.36(e)(9). Accordingly, FDA is modifying the sample language provided by the petitioner for a new § 101.36(e)(9) and is proposing to provide in that paragraph that quantitative information by weight (or volume, if permitted) may be declared on either a “per unit” or “per day” basis

in addition to the required ‘per serving’ basis. The agency is also proposing to redesignate existing paragraphs (c)(9), (c)(10) and (c)(11) of § 101.36 as (c)(10), (c)(11), and (c)(12), respectively, and to revise the reference in (c)(12) accordingly.

As is the case when nutrient information is given in additional columns as shown in current § 101.36(e)(10)(ii) and (e)(10)(iii), FDA believes that it is critical that clearly labeled column headings are provided to prevent consumer confusion about the information. Therefore, FDA is also proposing to provide a sample label in new § 101.36(e)(11)(viii) of a suggested format for a dietary supplement providing information on both a ‘per serving’ and ‘per day’ basis, FDA requests comments on the proposed changes.

The regulation specifying nutrition labeling requirements for dietary supplements will become effective March 23, 1999, and many dietary supplement manufacturers are currently making label changes necessary to come into compliance with those requirements. Although the agency does not expect to complete this rulemaking in time for the ‘per day’ information to be incorporated as part of the current changes, it has considered whether the information should be allowed on an interim basis prior to completion of the rulemaking so that firms wishing to incorporate it now with the other changes may do so. Because the agency believes that the proposed ‘per day’ information would not be misleading, FDA does not intend to object to manufacturers declaring information on a ‘per day’ basis prior to issuance of a final rule, provided it is presented in a manner consistent with this proposal. However, manufacturers should be aware that a final rule on this issue may differ from this proposal and that they would then be required to change their labels to conform to the final rule.

IV. Analysis of Impacts

A. Benefit/Cost Analysis

FDA has examined the impacts of this proposed rule under Executive Order 12866. Executive Order 12866 directs agencies to assess the costs and benefits of available regulatory alternatives

and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects; distributive impacts; and equity). According to Executive Order 12866, a regulatory action is “economically significant” if it meets any one of a number of specified conditions, including having an annual effect on the economy of \$100 million or adversely affecting in a material way a sector of the economy, competition, or jobs. A regulation is considered “significant” under Executive Order 12866 if it raises novel legal or policy issues. FDA finds that this proposed rule is neither an economically significant nor a significant regulatory action as defined by Executive Order 12866.

In addition, FDA has determined that this rule does not constitute a significant rule under the Unfunded Mandates Reform Act of 1995 requiring cost-benefit and other analyses. A significant rule is defined in section 1531(a) of the Unfunded Mandates Reform Act of 1995 as “a Federal mandate that may result in the expenditure by State, local, and tribal governments in the aggregate, or by the private sector, of \$100,000,000 (adjusted annually for inflation) in any 1 year.”

Finally, in accordance with the Small Business Regulatory Enforcement Fairness Act of 1996, the administrator of the Office of Information and Regulatory Affairs of the Office of Management and Budget has determined that this proposed rule is not a major rule for the purpose of congressional review.

FDA is proposing to allow the nutrition labeling of dietary supplements to present the quantitative amount by weight (or volume, if permitted) and the percent of Daily Value of a dietary ingredient on a “per day” basis in addition to the required “per serving” basis. This action provides manufacturers of dietary supplements flexibility to voluntarily present additional label information to consumers. This rule will result in costs and benefits only to the extent that firms elect to take advantage of the option of presenting information on a “per day” basis. No firm will bear the cost of redesigning labels unless it believes that the claim will result in increased sales of its product.

B. Small Entity Analysis

FDA has examined the impacts of this proposed rule as required by the Regulatory Flexibility Act (5 U.S.C. 601–612). If a rule has a significant impact on a substantial number of small entities, the Regulatory Flexibility Act requires agencies to analyze options that would minimize the economic impact of that rule on small entities. Under the Regulatory Flexibility Act (5 U.S.C. 605(b)), the agency certifies that this proposed rule will not have a significant impact on a substantial number of small entities.

This proposed rule would provide for voluntary, ‘per day’ labeling of dietary supplements. Because “per day” labeling would be permitted and not required, a firm, including any small firm, will change its labeling and incur costs only if the benefits to it (e.g. increased sales) exceed the costs. FDA further notes that small product lines from certain small firms are exempt from the dietary supplement nutrition labeling requirements provided no claims are made.

V. The Paperwork Reduction Act of 1995

This proposed rule contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The title, description, and respondent description of the information collection provisions are shown in this section of this document with an estimate of the annual reporting burden. Included in the estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing each collection of information.

FDA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of FDA’s functions, including whether the information will have practical utility; (2) the accuracy of FDA’s estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the

burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Title: Food Labeling: Nutrition Labeling of Dietary Supplements on a “Per Day” Basis.

Description: Section 403(q)(5)(F) of the act provides that dietary supplements shall bear nutrition labeling in a manner that is appropriate for the product and that is specified in regulations issued by FDA. FDA issued regulations establishing the requirements for nutrition labeling in §101.36 in the September 23, 1997, final rule. FDA is proposing to amend its nutrition labeling regulations for dietary supplements to provide that firms may voluntarily present the quantitative amount and the percent of Daily Value of dietary ingredients on a “per day” basis in addition to the required “per serving” basis, if a recommendation is made on the label that the dietary supplement be consumed more than once per day. These proposed provisions are in response to a citizen petition submitted by a manufacturer and marketer of dietary supplements. This proposed action would provide suppliers of dietary supplements flexibility to present additional label information voluntarily to consumers.

Respondent Description: Suppliers of dietary supplements.

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN I

21 CFR Section	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Hours per Response	Total Annual Hours	Total Operating Costs
101.36(e)	85 ^t	10	850 ^t	0.25	213	\$83,000 ^t

^t There are no capital or maintenance costs associated with this collection of information

These estimates are based on agency communications with industry (Refs. 1, 2, and 3) and FDA’s knowledge of, and experience with, food labeling. FDA estimated in the September 23, 1997, final rule (62 FR 49826 at 49846) that there were a maximum of 850 suppliers of dietary supplements and that, on average, each supplier had 40 products whose labels required revision. FDA estimates that only 10 percent, or 85, of the dietary supplement suppliers would revise the labels of their products to incorporate nutrition levels for the daily use of their products. FDA also estimates that daily use levels for nutrition information would generally be placed on at most 25 percent, or at most 10, of a firm’s estimated 40 products, although this number would vary

by firm based on the types of products that it produces. FDA also believes that the burden associated with the proposed disclosure of nutrition information on a daily use basis for dietary supplements would be a one-time burden for the small number of firms that would decide voluntarily to add this additional information to the labels for their products, separate from any other label changes for their products. FDA estimates that at least 90 percent of firms would coordinate addition of daily use nutrition information with other changes in their labels, in which case the voluntary cost of transmitting the information to consumers in labeling would be subsumed almost entirely in the cost of these other voluntary or required labeling changes. The incremental cost for these 76 firms would be approximately \$50 per label for 760 labels, or \$38,000 total. For the remaining 9 firms that would not coordinate changes with other labeling changes, FDA estimates that the cost would be approximately \$500 per label for 90 labels, or \$45,000 total. The estimated total operating costs in Table 1 are, therefore, \$83,000 total. Respondents are already required to disclose the quantitative amount and percent of Daily Value of dietary ingredients per serving as part of the nutrition information for dietary supplements. Respondents may also provide such information on a per unit basis. The information provided for under the proposed rule would be generated by simple extrapolation from that information.

In compliance with 44 U.S.C. 3507(d), the agency has submitted the information collection provision of the proposed rule to OMB for review. Interested persons are requested to send comments regarding information collection by *(insert date 30 days after date of publication in the Federal Register)*, to the Office of Information and Regulatory Affairs, OMB (address above), ATTN: Desk Officer for FDA.

VI. Environmental Impact

The agency has determined under 21 CFR 25.30(k) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

VII. References

The following references have been placed on display in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Memorandum of telephone conversation of August 10, 1998, between James C. Lassiter, Amway Corp., and Gerad L. McCowin, Office of Food Labeling, FDA.
2. Memorandum of telephone conversation of August 20, 1998, between Paul Bolar, Pharmavite Corp., and Gerad L. McCowin, Office of Food Labeling, FDA.
3. Memorandum of telephone conversation of August 20, **1998**, between Mike Bradley and Bill Cochrane, Leiner, Inc., and Gerad L. McCowin, Office of Food Labeling, FDA.

VIII. Comments

Interested persons may by *(insert date 75 days after date of publication in the **Federal Register**)* submit to the Dockets Management Branch (address above) written comments regarding this proposal, except that comments regarding information collection are to be submitted to the Office of Information and Regulatory Affairs, OMB (address above), by *(insert date 30 days after date of publication in the **Federal Register**)*. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

IX. Effective Date

The agency is proposing that any final rule that may issue based upon this proposed rule become effective 30 days after its date of publication in the **Federal Register**.

List of Subjects in 21 CFR Part 101

Food labeling, Nutrition, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR part 101 be amended as follows:

PART 101—FOOD LABELING

1. The authority citation for 21 CFR part 101 continues to read as follows:

Authority: 15 U.S.C. 1453, 1454, 1455; 21 U.S.C. 321,331,342, 343, 348, 371.

2. Section 101.36 is amended by removing paragraph (b)(2) (iv); by redesignating paragraphs (e)(9), (e)(10), and (c)(11) as paragraphs (e)(IO), (c)(11), and (e)(12), respectively; by adding new paragraph (e)(9); by adding paragraph (c)(11)(viii) to newly redesignated paragraph (c)(11); and by revising newly redesignated paragraph (c)(12) to read as follows:

§ 101.36 Nutrition labeling of dietary supplements.

* * *

(e) * * *

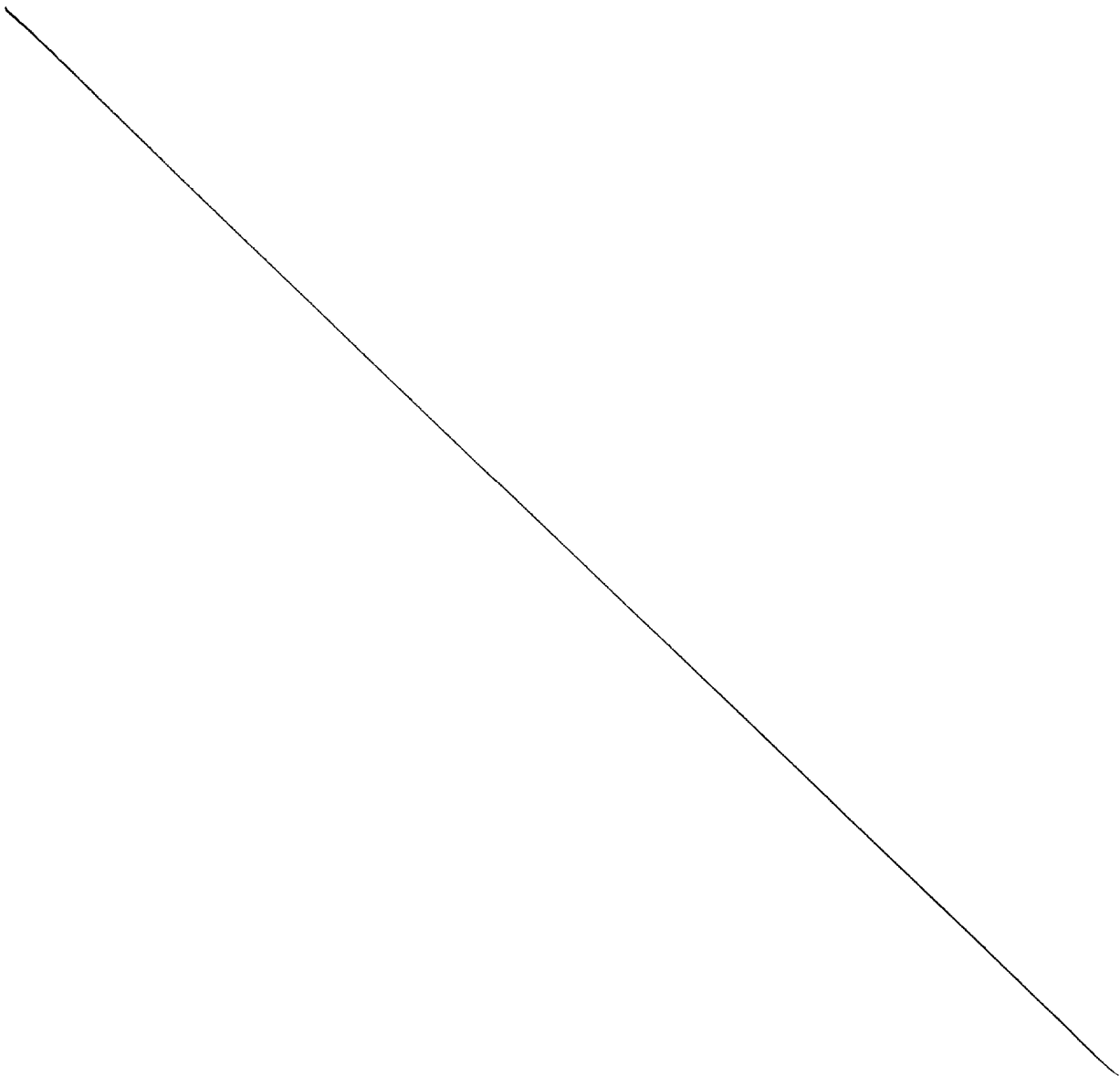
(9) The quantitative amount by weight (or volume, if permitted) and the percent of Daily Value may be presented on a “per unit” basis in addition to on a “per serving” basis, as required in paragraph (b)(2)(ii) and (b)(2) (iii) of this section. Alternatively, if a recommendation is made on the label that a dietary supplement be consumed more than once per day, the total quantitative amount and the percent of the Daily Value that will be consumed per day of each dietary ingredient may be presented. The “per unit” or “per day” information shall be presented in additional columns to the right of the “per serving” information and shall be clearly identified by appropriate headings as illustrated in paragraph (c)(11)(viii) of this section.

* * *

(11)* * *

[INSERT GRAPHIC HERE]

(12) If space is not adequate to list the required information as shown in the sample labels in paragraph (c)(11) of this section, the list may be split and continued to the right as long as the headings are repeated. The list to the right shall be set off by a line that distinguishes it and



- (vii) Dietary supplement illustrating “per serving” and “per day” information

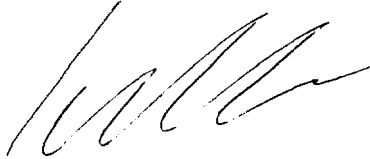
Supplement Facts				
Serving Size 1 Caplet				
	Per Caplet		Per Day (3 Caplets)	
	Amount	% Daily Value	Amount	% Daily value
Calcium (as calcium citrate)	500 mg	50%	1500 mg	150%
Vitamin D (as cholecalciferol)	125 IU	31%	375 IU	93%

sets it apart from the dietary ingredients and percent of Daily Value information given to the left.

The following sample label illustrates this display:

* * * * *

Dated: January 4, 1999
January 4, 1999



William K. Hubbard
Associate Commissioner
for Policy Coordination

CERTIFIED TO BE A TRUE COPY OF THE ORIGINAL



[FR Dec. 98-'? '??' Filed '? '??' '98: 8:45am]

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